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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/693,301	10/24/2003	Gary K. Schwartz	702-A-US	1477

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LAW OFFICES OF ALBERT WAI-KIT CHAN, LLC
141-07 20TH AVENUE, SUITE 604
WORLD PLAZA
WHITESTONE, NY 11357

EXAMINER

MARTIN, PAUL C

ART UNIT PAPER NUMBER

1655

DATE MAILED: 04/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	10/693,301		SCHWARTZ, GARY K.	
	Examiner		Art Unit	
	Paul C. Martin		1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 February 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31-38, 41 and 42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31-38, 41 and 42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>02/06/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 31-38, 41 and 42 are pending in this application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

All objections and rejections not repeated in the instant Action have been withdrawn due to Applicant's response to the previous Action.

This rejection is maintained for reasons of record set forth in the paper mailed 11/01/05, repeated below:

Slightly altered to take into consideration Applicant's amendment to the claims filed 02/06/06.

Claim Rejections - 35 USC § 112

Claim 34 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The MPEP states that for a generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP § 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. MPEP § 2163. Although the MPEP does not define what constitute a sufficient number of representative species, the courts have indicated what do not constitute a representative number of species to adequately describe a broad generic.

In re Gostelli, the courts determined that the disclosure of two chemical compounds within a subgenus did not describe the subgenus. *In re Gostelli*, F.2d at 1012, USPQ2d at 1618.

As stated *supra*, the MPEP states that the written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable, that Claims 34 is a broad generic, with respect to all possible protein kinase-c inhibitors. The possible variations as disclosed in the specification are limitless, and examples reflecting the variety of possible species in the genus are not provided.

Response to Arguments

Applicant's arguments filed 02/06/06 have been fully considered but they are not persuasive. Applicant's arguments are moot because the Exhibits A and B were not included with the response.

Claim Rejections - 35 USC § 102

Claims 31-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Hong-fen *et al.* (2001) as evidenced by Xu *et al.* (1994) and Das *et al.* (1995). *

Hong-fen *et al.* teaches the treatment of solid tumors comprising administering to rats an effective amount of *Coptis chinensis* extract (Pg. 1947, Abstract and Pg. 1948-49, Paragraphs 2.2-2.5) which further comprises a protein kinase-c inhibitor. Compounds found in ACNO such as *Curcuma zedoaria* and *Salvia miltiorrhiza* are known protein kinase-c inhibitors. (Xu *et al.* (abstract only) and Das *et al.* (Column 2, Lines 34-37)

*These references are cited merely to relay inherent properties of *Curcuma zedoaria* and *Salvia miltiorrhiza* and are not used as a basis for rejection *per se*.

Response to Arguments

Applicant claims that Hong-fen does not teach a method for treating cancer in a subject comprising administering to the subject an effective amount of *coptis chinensis* extract because the reference teaches administration of a mixture of herbs, a component of which is *coptis chinensis*, and that the reference does not enable uses of the extract of *coptis chinensis* for cancer treatment.

The Applicant's rejection is not found persuasive for the following reasons:

Applicants use of the language "comprising administering to the subject an effective amount of aqueous *coptis chinensis* extract", according to the MPEP;

"The transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., > Mars Inc. v. H.J. Heinz Co., 377 F.3d 1369, 1376, 71 USPQ2d 1837, 1843 (Fed. Cir. 2004)"

The reference teaches the administration of an effective amount of aqueous extract, of which *coptis chinensis* is a constitutive component to treat the spread of cancer in rats (Pg. 1949, Column 1, Lines 8-42 and Column 2, Lines 1-13 and Pg. 1951, Fig. 2).

Claim Rejections - 35 USC § 103

Claims 31-38, 41 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hong-Fen *et al.* (2001) in view of Xinxian, 6,290,995 and Alloatti *et al.* (1998).

Hong-fen *et al.* teaches a method for treating cancer in a subject by administering an effective amount of an extract containing *coptis chinensis*, and other therapeutic agents, which are known protein kinase-c inhibitors as discussed *supra*.

Hong-fen *et al.* does not teach using a microtubule destabilizing therapeutic agent that is a taxol or "taxol-like". Nor does the reference teach any sequence of administration of the *coptis chinensis* and therapeutic agent.

Xinxian teaches that taxol is an anti-cancer drug that has the characteristic of promoting the assembly of microtubules. Xinxian notes that taxol has the associated problem of being poorly water soluble. Xinxian further teaches the use of the cancer treating extracts from two plants, one of which is high in berberine, an active component found in *coptis chinensis*. (Column 1, Lines 26-36 and Table 1)

Aloatti *et al.* teaches the use of taxol and taxol-analogs as a known anti-cancer treatment that acts to inhibit microtubule disassembly, active against a wide range of solid tumors, though with some serious clinical side effects. (Pg. 561, Column 1, Lines 1-14).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to include a microtubule “destabilizing” agent in a sequential regimen with the extract containing *coptis chinesis* and a protein kinase-c inhibitor and would have had motivation to do so because sequential treatments allow the researcher to assay efficacy, toxicity, possible side effects, or benefits of each compound separately. Further, the compounds act through different mechanisms and pathways and may work under different time frames.

It is also noted that since taxols are not readily water soluble, a second preparation would likely be needed since administration in tandem with the *coptis* extract would not be suitable.

Response to Arguments

The Applicant argues that because the references teach the use of more than one herb in the treatment of cancer that they cannot teach or make obvious the claimed invention of using a single herb extract to treat cancer.

The Applicant's arguments are not found persuasive for the following reasons, as discussed in the rejection under 35 USC § 102 (b) above the language of the claim is interpreted such that the teachings of Hong-fen combined with the teachings of the other references teach and make obvious the claimed invention wherein an herbal mixture of which *coptis chinensis* is a constituent component and is used to treat cancer in a subject.

Conclusion

No Claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Art Unit: 1655

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul C. Martin whose telephone number is 571-272-3348. The examiner can normally be reached on M-F 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Paul Martin
Examiner
Art Unit 1655

03/03/06

PATRICIA LEITH
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read "Patricia Leith", written over a circular stamp.